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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,014	GEPHART ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,21,24-34 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 21, 24-34,36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks (USP 5,096,669) in view of Patko et al (USP 6,153,085) and Smith (USP 5,108,889).

3. Lauks disclosed all the limitations of the set forth system (see rejection of 9-11-2003), but did not explicitly set forth an indicia unique for each test cell, nor did Lauks set forth a reader for the indicia. Patko teaches in an alternate electrochemical sensor that a barcode can be utilized for storing information about the electrochemical device and that each barcode should be unique for that electrochemical sensor (col. 10, ll. 48-56). The barcode of Patko allows more information to be transmitted to the instrument than can be transmitted by the notches of Lauks including calibration and quality control information and whether the sensor has been previously inserted into the instrument (col. 10, ll. 48-56). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Patko for the system of Lauks in order to transmit more information about the test cell to the instrument including whether the strip has been previously inserted into the sensor. This is particular relevant to the teaching of Lauks, which is drawn to a sensor that is meant to be utilized once and discarded (see the title and the last sentence of the abstract). Preventing the reuse of the test strip would potentially prevent a false analysis of a patient's blood.

4. Applicant has amended claim 1 to set forth the presence of a unique identification code for the electronic instrument. However, this claimed identification code would read on the well established practice of having a serial number associated with an instrument. Smith teaches the presence of such a serial number for its instrument. See col. 52, l. 66 through col. 53, l. 8 and col. 56, ll. 57-65. Having a serial number be associated with the instruments allows the instrument to be uniquely identified for inventory, tracking and customization purposes. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Smith for the system of Lauks and Patko in order to better track and inventory the instrument. With respect to the claim language "that provides positive identification of each test result provided by the instrument", this would appear to constitute the intended use of the unique identification code and the intended use need not be given further due consideration in determining patentability of an apparatus.

5. Alternatively, even if the examiner construed this limitation as being explicitly structural feature of the apparatus, storing the instruments identification code with each data file would have been obvious. In particular, Lauks teaches that the instrument should have the capability of outputting the data such that it can be stored and/or further processed. See col. 10, ll. 35-44. Smith teaches that each instrument can have customized characteristics including units of operation and look-up tables. See col. 52, l. 66 through col. 53, l. 8 and col. 56, ll. 57-65. If each instrument is customized, then it would have been obvious to have information about the instrument that prepared the data stored with the data files such that when the data is either further processed or reexamined at a latter time, the operator analyzing the data would be able to

determine both when and where the data was taken as well as appropriately account for any customization.

6. With respect to the various dependent claims, see the rejection of 9-11-2003.

7. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Tomita (USP 4,797,188).

8. Lauks, Patko and Smith teach all the limitations of the claims, but do not explicitly provide the detailed structure for the test cell. Tomita teaches in an alternate cell for monitoring the constituents in aqueous samples that a typical test cell for measuring concentrations of things such as potassium includes an electrolyte (i.e. an internal solution) 19 coated over one of the electrodes (fig. 1). Internal solutions are a well established means for ensuring appropriate electrochemical contact between the metal electrode and the sample and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Tomita for the system of Lauks, Patko and Smith in order to ensure appropriate electrochemical contact between the metal electrode and the sample. Tomita also teaches the use of a gelled form of the internal solution as well as an ion selective membrane 20 which has been impregnated with an appropriate chemical species over that gelled solution (col. 4, l. 62 through col. 5, l. 38).

9. Claims 25 and 29 (and claims 27 and 28 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Jakubowicz et al (USP 4,798,705).

10. Lauks, Patko and Smith set forth all the limitations of the claims, but did not explicitly set forth the use of either a liquid crystal display or a thermal printer. Jakubowicz discloses that

both those forms displays and printers are well known in the analytical art (col. 3, ll. 3-6). With respect to claims 27 and 28 in the alternative), Jakubowicz also shows that the printer and keyboard of a system can be integrated into the instrument (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks, Patko and Smith because the substitution of one known means for display or printer for another known means requires only routine skill in the art. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks, Patko and Smith because integrating the keyboard and printer into the single device simplifies the system making it easier to handle.

11. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks, Patko and Smith in further view of Betts et al (USP 5,405,510).

12. Lauks, Patko and Smith set forth all the limitations of the claims, but did not explicitly identify the use of the RS 232 interface or the use of an internal power source. Betts discloses that both that particular interface as well as the use of batteries is well known in the art (col. 14, ll. 6-9 and col. 19, ll. 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Betts for the system of Lauks , Patko and Smith because the use of standard interfaces and power sources requires only routine skill in the art. With respect to the batteries being rechargeable, rechargeable batteries are an obvious and conventional form of battery and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize them because they would save the system operator money over the long term.

Response to Arguments

13. With respect to the 112 first paragraph rejection, applicant's argument of support for this limitation is persuasive and the examiner has withdrawn this rejection. The examiner has also withdrawn the outstanding 112 second paragraph in view of the applicant's discussion of what the text of paragraph 041 and original claim 35 was drawn to, which appears to closely mirror the examiner's interpretation of this passage from the previous office action. See last two lines of p. 2 of the final rejection of 2-8-2005.

14. With respect to the art rejection, applicant, after initially agreeing with the examiner that it is Lauks intention to not utilize its sensors more than once (i.e. it is disposable), then urges that there is no teaching or suggestion that would preclude or prevent the sensor from being used again. The examiner is entirely confused by this argument. If Lauks wanted a sensor to be utilized only once, then one clearly would have been motivated to preclude or prevent said sensor from being used again. Applicant also urges that Lauks does not teach a unique serial number. That may be true, but that is the purpose of the teaching of Patko. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

15. With respect to the combination of Lauks and Patko, applicant urges that there is no linking teaching in the Patko patent that would suggest the use of a serial number for a device like described by Lauks. This is entirely unpersuasive. Patko taught the use of a bar-code that allowed the storage of information about the sensor and prevented the reuse of the sensor (col.

10, ll. 40-55). Lauks utilizes notches to identify the sensor. Hence, Lauks already recognized that one should provide a means for at least identifying the type of sensor being utilized. One possessing ordinary skill in the art would clearly recognized that a bar-code, like that disclosed by Patko, would have been capable of providing that information in an analogous manner to that of the notches of Lauks. Furthermore, because Lauks is drawn to a disposable sensor, one possessing ordinary skill in the art would clearly recognized that a means to prevent reuse of a sensor would have been germane to the teaching of Lauks. Patko provides an explicit teaching of a means for preventing reuse of an electrochemical sensor. Hence, the examiner has provided suitable linking between the two teachings to support the obviousness rejection.

16. With respect to the rejection relying on Smith, applicant urges that there is no motivation to combine Smith and Lauks. First, the examiner notes that applicant's earlier arguments appear to contradict that conclusion. In particular, applicant urged at the bottom of p. 9 that "[o]ne skilled in the art would recognize the merits of being able to identify which instrument provided a particular test result (e.g. traceability and the like)". The examiner was relying on Smith for this very reason, namely to be able to have a serial number be associated with the instrument, which allows the instrument to be uniquely identified for inventory, tracking (i.e. traceability and the like) and customization purposes. See paragraph 8 from the previous final rejection (reprinted above as well). Hence, applicant appears to largely agree with the examiner on p. 9 of the response only to disagree by p. 13 of the response. Second, applicant's traversal on p. 13 is unpersuasive on its own merits. Initially it is noted that applicant's arguments appear to concern the issues the examiner raised in paragraph 9 of the final rejection without addressing the arguments in paragraph 8 of the final rejection. Attaching that serial number (i.e. the unique

identification code) to the data has been treated as intended use. All that claim 1 *structurally* requires over the teachings of Lauks and Patko is a "unique identification code" for the instrument. Smith discloses a unique identification code for its instrument and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize that code for the instrument of Lauks and Patko. Whether or not one utilizes that code with each test result constitutes intended use. See paragraph 8 from the previous office action (reprinted above as well). With respect to the applicant's response to paragraph 9 of the final rejection, applicant urges that Smith gave no indication of transmitting the serial number with the data being transferred. The examiner agrees with the applicant on this point and has admitted as much in paragraph 9 of the final rejection. However, just because Smith didn't explicitly suggest providing this code with the data doesn't mean that it would not been obvious to do so. In short, the examiner urged in paragraph 9 that if each sensing instrument were unique, then it would have been obvious to one of ordinary skill in the art to attach that serial number to the data that was obtained by that instrument. Applicant urges that motivation to combine the references must be found in the references (MPEP 2143.01). This is not entirely correct. Motivation or suggestion may come from the references themselves, but it can also come from knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

17. Applicant urges that Lauks and Patko are not properly combinable. This argument would appear to be just a variation on applicant's earlier assertion that Lauks and Patko are not suitably

linkable. The examiner addressed the issue of the combination of Lauks and Patko above and will not reiterate those arguments here.

18. Applicant's remaining arguments concerning Tomita, Jakubowicz and Betts appear to rely on the perceived failings of the combination of Lauks, Patko and Smith. Because those earlier arguments weren't found persuasive (see above), these later arguments are similarly unpersuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. Until July 15, 2005, the fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Starting July 15, 2005, the fax number will be 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
July 12, 2005

KAJ K. OLSEN
PRIMARY EXAMINER